

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 20 1987

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File No. 1812-GER. Nitrosamine data for new  
trifluralin formulation (Trilin DF). MRID# 40238401  
[RCB# 2497]

FROM: Richard Loranger, Chemist, *R. Loranger*  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

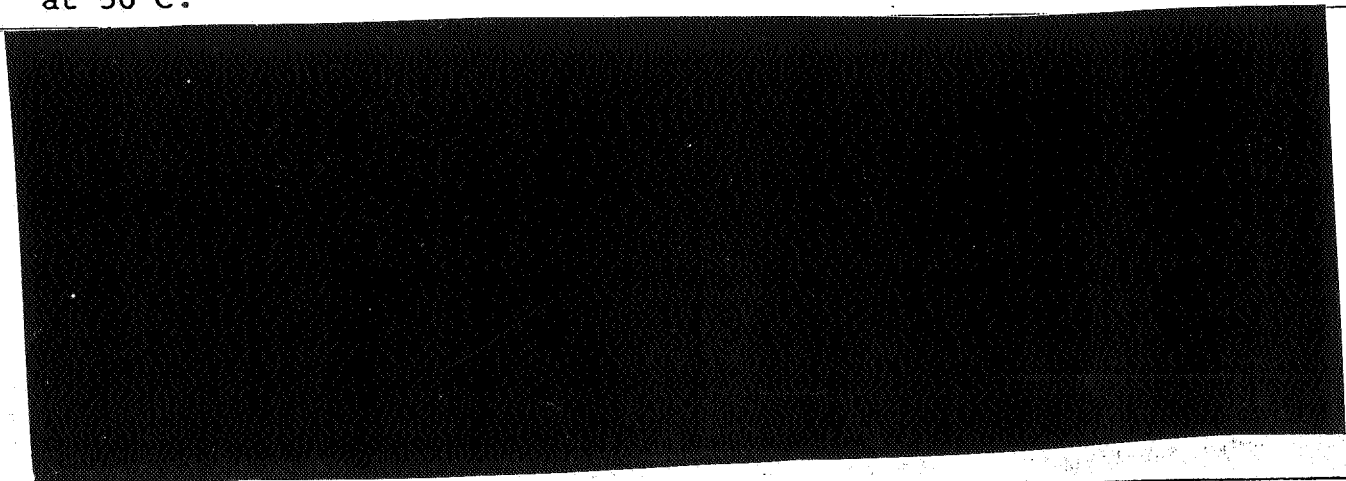
THRU: Andrew Rathman, Section Head  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769) *ARR*

TO: Richard Mountfort, PM 23  
Registration Division (TS-767)

Griffin Ag Products, Inc., has applied for registration of a new formulation containing the herbicide trifluralin (a,a,a-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine). We have been requested to review the nitrosamine data for this 80% active dry flowable material known as Trilin DF and comment on the need for residue data.

The submitted nitrosamine analyses were conducted by the Analytical Services Laboratory of Thermedics Inc. Three reports from the latter are included in the data package. The 3/4/87 report deals with analyses of five batches of the formulation (012, 104A, 105A, 106A, 107A) Two later studies describe analyses of lot 105A after 30 and 90 days of storage in polyethylene containers at 50°C.

INFORMATION WHICH MAY REVEAL QUALITY CONTROL PROCEDURES IS NOT INCLUDED



Page 12 is not included in this copy.

Pages \_\_\_\_\_ through \_\_\_\_\_ are not included in this copy.

---

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
  - ☐ Identity of product impurities
  - ☐ Description of the product manufacturing process
  - ☒ Description of product quality control procedures
  - ☐ Identity of the source of product ingredients
  - ☐ Sales or other commercial/financial information
  - ☐ A draft product label
  - ☐ The product confidential statement of formula
  - ☐ Information about a pending registration action
  - ☐ FIFRA registration data
  - ☐ The document is a duplicate of page(s) \_\_\_\_\_
  - ☐ The document is not responsive to the request
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---

INFORMATION WHICH MAY REVEAL QUALITY CONTROL PROCEDURES IS NOT INCLUDED

[REDACTED]

The other issue regarding registration of this product is the need for residue data. The latter have been generated using emulsifiable concentrates (EC). Usually we accept data from EC's to cover uses of dusts and dry flowable products. Since most applications of trifluralin are early season (i.e., prior to or shortly after crop emergence), we see no need for separate residue data for Trilin DF, providing that application rates and timings are the same as those of registered EC's.

#### CONCLUSIONS AND RECOMMENDATION

1. The submitted nitrosamine analyses of Trilin DF are valid. This product contains total nitrosamines [REDACTED] when stored from 0 to 90 days after production. These levels are below the 0.8 ppm ceiling permitted by the Trifluralin PD 4. The registrant should be told to submit a revised Confidential Statement of Formula stating a maximum of 0.80 ppm total nitrosamines (not [REDACTED] as on the present CSF).

2. The registrant has a valid analytical method for measuring nitrosamines in his trifluralin products as part of a quality control procedure (required by Trifluralin PD 4).

3. Provided that the proposed application rates and timings for Trilin DF are the same as those on labels of registered EC products (or such that they would lead to lower residues; eg., lower rates, longer preharvest intervals), residue data are not necessary for this formulation.

We have no objections to the registration of Trilin DF provided that the CSF is modified as stated in Conclusion 1 and the proposed uses are as specified in Conclusion 3. However, Griffin should be told that the existing residue chemistry data gaps from the Trifluralin Registration Standard apply to this product and must eventually be filled for long term registration.

*Griffin  
3/15/87 (D)  
applies  
RFM*

cc: Circu, RF, Trifluralin SF, Nitrosamine SF, Reviewer, PMSD/ISB  
RDI:Section Head:ARRathman:8/19/87:RDSchmitt:8/19/87  
TS-769:RCB:517-7324:RAL:ral(12):CM#2:RM.810:Date:8/19/87